K013973

FEB 2 6 2002

510(k) Summary

Name and Address of Submitter

VISTAKON®, Division of Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256
Contact: James W. Parziale
Phone: (904) 443-1808
Date Prepared: November 28, 2001

Identification of Device

- Trade Name: ACUVUE® Brand (etafilcon A) soft (hydrophilic) contact lenses; clear and tinted (visibility and/or cosmetic) with UV blocker; for daily wear
- Common or Usual Name: Soft (hydrophilic) Contact Lens (daily wear)
- Classification: Class II under 21 CFR 886.5925

Predicate Devices

The predicate devices are the:

- ACUVUE® Brand (etafilcon A) soft (hydrophilic) Contact Lenses clear and visibility tinted with UV blocker cleared most recently via K994324 on February 23, 2000, and
- ACUVUE® 2 *COLOURS* Brand (etafilcon A) soft (hydrophilic) Contact Lens with UV blocker cleared most recently via K010114 on April 11, 2001.

The additional indication is substantially equivalent to the labeling of:

- CIBA Vision Corporation, Focus® DAILIES® (nefilcon A) ONE-DAY CONTACT LENSES most recently cleared via K003586 on February 8, 2001.

Description of Device

The device descriptions do not change from those cleared under K994324 and K010114.

Intended Use

The ACUVUE® Brand Contact Lenses (spherical) are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism.

The ACUVUE® Brand (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lenses are indicated for daily wear to enhance or alter the apparent color of

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Intended Use, continued

the eye for lenses with cosmetic tint and for the correction of distance and near vision in presbyopic, aphakic or not-aphakic persons with non-diseased eyes who may have 0.75 D or less of astigmatism.

The ACUVUE® Brand (etafilcon A) Soft (hydrophilic) TORIC Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D or less of astigmatism.

The ACUVUE® Brand (etafilcon A) Soft (hydrophilic) TORIC BIFOCAL Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and for the correction of distance and near vision in presbyopic aphakic or not-aphakic persons with non-diseased eyes who may have 10.00 D of astigmatism or less.

ACUVUE® Brand (etafilcon A) Soft (hydrophilic) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Practitioners may prescribe the lens for either single-use disposable wear (See "Wearing Schedule").

Reason For 510(k)

The reason for the 510(k) is to revise the "Wearing Schedule" section of the Package Insert and the "Introduction" section of the Patient Instruction Guide Disposable Daily Wear to include the following statements:

When worn on a daily disposable basis, ACUVUE® Brand (etafilcon A) Soft (hydrophilic) Contact Lenses provide improved comfort for patients who experience mild discomfort and itching associated with allergies during contact lens wear compared to lenses replaced at intervals of greater than 2 weeks.

Clinical research has shown that when worn on a daily disposable basis, ACUVUE® Brand (etafilcon A) Soft (hydrophilic) Contact Lenses provided improved comfort for 2 out of 3 patients who reported suffering from itching and mild discomfort associated with allergies during contact lens wear.

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510(k) Summary, Continued

Technological Characteristics	The technological characteristics do not change. They are the same as previously submitted in K994324 and K010114.
Non-Clinical Studies	Non-clinical studies (chemistry, toxicology, microbiology, shelf-life, and leachability) on the lens material were not conducted since the lens material, etafilcon A, does not change.
Clinical Studies	**This 510(k) describes a labeling modification to the "Wearing Schedule" section of the Package Insert and to the "Introduction" section of the Patient Instruction Guide Disposable Daily Wear.** There is no change in lens material, the manufacturing process, nor the parameters and properties, therefore, the clinical data previously submitted in K994324 and K010114 supports the clinical safety of the subject device. An additional study supports the proposed labeling modification.
Conclusions	Additional safety studies were not conducted, therefore, the conclusions drawn from studies previously submitted in K994324 and K010114 support the non-clinical and clinical safety of the subject device. **The additional study supports the proposed labeling statement to be added to the Package Insert and the Patient Instruction Guide Disposable Daily Wear.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Vistakon, Division of Johnson & Johnson
Vision Care, Inc.
c/o James W. Parziale
7500 Centurion Parkway, Suite 100
Jacksonville, FL 32256

Re: K013973
Trade/Device Name: ACUVUE® Band (etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: November 30, 2001
Received: December 3, 2001

Dear Mr. Parziale:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known):

Device Name: ACUVUE® Brand (etafilcon A) soft (hydrophilic) contact lenses; clear and with tint (visibility and/or cosmetic) with UV blocker; for daily wear

Indications for Use:

The ACUVUE® Brand Contact Lens (spherical) are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism.

The ACUVUE® Brand (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and for the correction of distance and near vision in presbyopic, aphakic or not-aphakic persons with non-diseased eyes who may have 0.75 D or less of astigmatism.

The ACUVUE® Brand (etafilcon A) Soft (hydrophilic) TORIC Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00 D or less of astigmatism.

The ACUVUE® Brand (etafilcon A) Soft (hydrophilic) TORIC BIFOCAL Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye for lenses with cosmetic tint and for the correction of distance and near vision in presbyopic aphakic or not-aphakic persons with non-diseased eyes who may have 10.00 D of astigmatism or less.

ACUVUE® Brand (etafilcon A) Soft (hydrophilic) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Eye Care Practitioners may prescribe the lens for single-use disposable wear (See "Wearing Schedule").

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter** _____

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

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